

# **EXHIBIT C**

Page 1

1 UNITED STATES DISTRICT COURT  
2 FOR THE DISTRICT OF NEW JERSEY  
3 CAMDEN VICINAGE  
4 MDL NO. 2875

5 IN RE: VALSARTAN, LOSARTAN, :  
6 AND IRBESARTAN PRODUCTS :  
7 LIABILITY LITIGATION :

8 THIS DOCUMENT RELATES TO :  
9 Gaston Roberts et al. v. :  
10 Zhejiang Huahai :  
11 Pharmaceutical Co., et al., :  
12 :  
13 Case No. 1:20-cv-00946-RMB-SAK:

14 Videotaped remote deposition of  
15 NADIM MAHMUD, M.D., taken in the above-entitled  
16 matter before Suzanne J. Stotz, a Certified  
17 Court Reporter (License No. 30XI00184500) and  
18 Notary Public of the State of New Jersey,  
19 taken on Friday, May 2, 2025, commencing at  
20 9:03 a.m. EDT.  
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23  
24  
25

<p style="text-align: right;">Page 122</p> <p>1 something is oftentimes based, first, on 2 animal studies. Is there anything 3 potentially relevant to humans to justify 4 doing a study. 5 You know, my recollection is that 6 there are studies for -- for each of the 7 things I mentioned, but I -- you know, I 8 can't -- I can't speak to the strength of 9 them off the top of my head. I'd have to 10 review them again. 11 BY MR. VAUGHN: 12 Q. Do you have an opinion if there's 13 more literature or less literature on benzene 14 causing liver cancer in humans than NDMA? 15 MS. ROSE: Object to the form. 16 THE WITNESS: No, I don't have an 17 opinion on that. I -- I haven't reviewed 18 the literature with respect to benzene 19 inasmuch depth as I have with NDMA as 20 pertain- -- pertaining to this case. 21 But I do recall that there are some 22 studies. I can't speak to the volume or 23 depth of them. 24 BY MR. VAUGHN: 25 Q. Okay. And then on this web page we</p>	<p style="text-align: right;">Page 124</p> <p>1 summary. 2 Q. And for -- for the layperson, it 3 would be two things, the scarring of the liver 4 plus the poor liver function to have cirrhosis, 5 correct? 6 MS. ROSE: Object to the form. 7 THE WITNESS: Yes. So I mean, I -- 8 I disagree a little bit with the 9 characterization there because, as I've 10 stated before, you can have cirrhosis 11 without having clear evidence of 12 derangement of liver synthetic function. 13 Oftentimes, that is seen later in the 14 progression of cirrhosis. 15 You know, perhaps -- again, I don't 16 know who makes this website or who's 17 responsible for the content, but, you 18 know, I'm not responsible. I -- I 19 don't -- I don't write this myself. You 20 know, Penn Medicine -- I have no idea who 21 actually writes this. 22 But I -- I assume it's filtered 23 through a lens to make this very 24 simplistic for patients to just broadly 25 understand what cirrhosis often means.</p>
<p style="text-align: right;">Page 123</p> <p>1 were on, it has common liver diseases; and it 2 has cirrhosis as a link. 3 MR. VAUGHN: If you'd go ahead and 4 drop the cirrhosis one, Kathryn, that will 5 be Exhibit 5. 6 (Whereupon, Exhibit 5, Penn 7 Medicine Cirrhosis - Symptoms and Causes, 8 was marked for identification.) 9 MS. AVILA: Okay. It should be in 10 there. 11 MR. VAUGHN: Okay. 12 BY MR. VAUGHN: 13 Q. And for -- the definition of 14 cirrhosis is scarring of the liver and poor 15 liver function. 16 Do you agree with that definition 17 of cirrhosis? 18 A. I -- I think it's a very, probably, 19 oversimplified definition of cirrhosis for the 20 purpose of the lay public. 21 I think I've already given you my 22 definition of cirrhosis, but, you know, I think 23 for -- for simplicity and communicating it to a 24 patient who might be visiting this website, I 25 think it's a -- it's a rudimentary layperson</p>	<p style="text-align: right;">Page 125</p> <p>1 And so yes, it means scarring of 2 the liver, and it can mean poor liver 3 function; but as I've stated previously, 4 you can have cirrhosis and actually have 5 relatively reserved liver synthetic 6 markers on your blood work. 7 BY MR. VAUGHN: 8 Q. And so do you disagree with the 9 information that Penn Medical is putting out to 10 the public? 11 MS. ROSE: Object to the form. 12 THE WITNESS: Like I said, I think 13 that my -- my understanding and nuanced 14 understanding of cirrhosis as a clinician 15 goes much more beyond what, you know, this 16 website is communicating to patients. 17 I think that, likely, they're 18 trying to keep things very simple to 19 provide at a high level, you know, some 20 understanding of what these medical terms 21 may generally mean. 22 I don't think their intention is 23 likely to be extremely detailed about the 24 technical definitions of cirrhosis. 25</p>

<p style="text-align: right;">Page 190</p> <p>1 Historically, we do -- we -- we 2 don't -- usually once we make a diagnosis of 3 cirrhosis, we regard the patient to have 4 cirrhosis moving forward, and we manage them 5 with the assumption that there is cirrhosis. 6 There are some scenarios like very 7 specific scenarios, where patients may have 8 some improvement in their -- their estimated 9 fibrosis, very, very specific scenarios. And 10 one scenario is Hepatitis C virus. That's 11 probably the best studied one where a patient 12 has chronic Hepatitis C. They develop 13 cirrhosis, and then they're treated with a 14 medication that can cure the Hepatitis C 15 entirely. 16 Those medications were, you know, 17 developed in, like 2015, 2016. And so now 18 we're able to cure Hepatitis C, and we've 19 observed over the past decade or so in 20 following these patients, that some of those 21 patients might go from F4, which is cirrhosis, 22 to F3. 23 The reason why I say it's a pretty 24 exceptional circumstance is a lot of those 25 patients the only reason -- the only cause of</p>	<p style="text-align: right;">Page 192</p> <p>1 correct? 2 A. Yes. 3 Q. And would thrombocytopenia be an 4 abnormal CBC result? 5 A. Yes, generally. Yeah. If the 6 platelet count's less than 150, that would be 7 regarded to be an abnormal CBC. 8 Q. I want to go back to your expert 9 report, which was Exhibit 1. I'll go ahead and 10 screenshare it, but feel free to look at it 11 yourself as well. 12 A. Okay. 13 Q. I want to go to page 18 right now. 14 I, first, want to direct you to this part of 15 your opinion, which is, "Cirrhosis refers to 16 significant scar tissue that impairs liver 17 function." 18 You agree with that, correct? 19 A. Yes. 20 Q. Okay. And that -- and that is what 21 Penn Medical is saying as well, correct, that 22 it's both the scar tissue plus the impaired 23 liver function? 24 A. Yes. 25 Q. Okay. And then you start talking</p>
<p style="text-align: right;">Page 191</p> <p>1 their liver disease was Hepatitis C, and 2 there's a very abrupt -- abrupt and complete 3 removal of that underlying cause of liver 4 disease. So that doesn't really translate 5 to -- to MASLD and MASH for the vast majority 6 of patients where, you know, to achieve that 7 abrupt transition, you need to have substantial 8 and sustained weight loss, which unfortunately, 9 is very tough for patients to the achieve. 10 MR. VAUGHN: Nina, I'm at a great 11 spot for a break if you want to do lunch 12 now. 13 MS. ROSE: Yeah. 14 Does that work for you, Doctor? 15 THE WITNESS: Yeah. 16 THE VIDEOGRAPHER: Off the record, 17 12:45. 18 (Whereupon, a lunch was taken.) 19 THE VIDEOGRAPHER: We are back on 20 the record at 1:25 p.m. 21 BY MR. VAUGHN: 22 Q. Welcome back, Doctor. 23 A. How are you doing? 24 Q. Good. Earlier we were talking 25 about how platelet counts are part of the CBC,</p>	<p style="text-align: right;">Page 193</p> <p>1 about FIB-4. 2 Is that what you were discussing 3 earlier as far as being able to diagnose 4 cirrhosis with? 5 MS. ROSE: Objection to the form. 6 THE WITNESS: Yeah. Not -- not -- 7 not in and of itself to diagnose the 8 cirrhosis, but as a tool to risk 9 stratify -- risk stratify patients with 10 chronic liver disease who may require 11 further testing to -- to rule in or rule 12 out cirrhosis. 13 BY MR. VAUGHN: 14 Q. And within Mr. Roberts' medical 15 records, does it ever mention FIB-4? 16 A. I did not see any mentions of 17 FIB-4. 18 Q. And you note that a FIB-4 of less 19 than 1.3 effectively rules out advanced 20 fibrosis. 21 Can you explain that? 22 A. Sure. So if you calculate the 23 FIB-4 for a patient, again, based on the age, 24 AST, ALT, and platelet count, if you get a very 25 low number, less than 1.3, that -- that patient</p>

<p style="text-align: right;">Page 354</p> <p>1 You know, we talked about the stage of 2 cancer that he was diagnosed with. It's 3 really important to highlight that when he 4 was diagnosed in, you know, April -- you 5 know, July/April of 2018, he did not have 6 early stage hepatocellular carcinoma. He 7 had multiple lesions. There were two 8 lesions that were clear -- clearly 9 LI-RADS 5 lesions that were, you know, 10 HCC, the largest of which, from my 11 recollection, was 5.8 centimeters in 12 diameter. 13 You don't get a 5.8-centimeter 14 diameter HCC overnight. That does not 15 occur quickly. That takes a long time to 16 get there, to that size. And fortunately, 17 this is something that's been studied in 18 great detail across many studies. There's 19 a lot of interest in understanding growth 20 rates of HCC so we can understand what to 21 expect in patients and how to 22 prognosticate. 23 And in my expert report, you know, 24 I cite the literature, and I give the 25 different ranges, the average tumor volume</p>	<p style="text-align: right;">Page 356</p> <p>1 BY MR. VAUGHN: 2 Q. Understood. And I was planning to 3 get to it if we had time in the deposition. 4 What's the fastest growth rate for 5 HCC? 6 A. Yeah. So, you know, we look at 7 this mostly in terms of tumor volume doubling 8 time. I'm pulling up my report to give you 9 very precise numbers. 10 Okay. So tumor volume doubling 11 time, again, these are -- these estimates are 12 aggregated. It's actually coming from a 13 meta-analysis of many different studies to get 14 as accurate of representation of the range of 15 growth rates as possible. 16 The most -- so if you take the 17 95-percent kind of confidence interval in terms 18 of one extreme to the other, the most sort of 19 aggressive growth rates are on the scale of 20 3.9 months for tumor volume doubling time. 21 And so I have table where I kind of 22 go through these calculations. The average is 23 about 4.6 months for tumor volume doubling 24 times, and the slower one are 5.3 months of 25 tumor volume doubling time.</p>
<p style="text-align: right;">Page 355</p> <p>1 doubling time, the extreme cases of very 2 aggressive growth and -- and very slow 3 growth. And I ran simulations for all of 4 those. 5 And no matter what assumption you 6 take, even if I assumed the most 7 aggressive form of hepatocellular 8 carcinoma with the fastest growth rates 9 that are observed in -- in -- you know, in 10 multiple observational studies, 11 Mr. Roberts would have already had HCC in 12 his liver prior to the time he was first 13 exposed to NDMA-contaminated Valsartan. 14 So there's no plausible way you can 15 say that NDMA, regardless of the dose, 16 could have caused it if it's already 17 there. So the temporality is -- is a 18 really key point in this case and one that 19 we didn't really talk about explicitly. 20 But I have to highlight it in the 21 context of this to explain why my opinion 22 doesn't change. Even if he had, 23 hypothetically, had a higher dose exposure 24 to NDMA, my view is that his cancer was 25 already there.</p>	<p style="text-align: right;">Page 357</p> <p>1 Q. So 3.9 months is the quickest 2 doubling time of HCC? 3 A. Tumor volume doubling time, yes. 4 Q. Is it your opinion that NDMA cannot 5 cause cirrhosis? 6 A. So I think, you know, in -- in 7 animal literature, you know, at a sufficiently 8 high dose, you know, I do think that NDMA can 9 likely cause hepatic fibrosis and likely 10 cirrhosis, you know, in, you know, rodent 11 studies, for instance. But I don't think 12 that's been demonstrated to any sufficient 13 degree in humans. 14 Q. Did you search for that? 15 A. Yes. 16 Q. What -- where -- what did you 17 search? 18 A. Yeah. So I had a range of 19 different searches. You know, I looked for, 20 you know, NDMA, you know, liver fibrosis, 21 liver, obviously hepatocellular carcinoma. I 22 looked, you know, nitrosamine, you know, liver 23 cirrhosis, hepatocellular carcinoma. 24 I did this specifically because in 25 the -- the plaintiff expert witness report, she</p>

90 (Pages 354 - 357)

<p style="text-align: right;">Page 410</p> <p>1 A. That's okay. Go ahead.</p> <p>2 Q. What does the word "indolent" mean?</p> <p>3 A. Sorry. Where are you looking?</p> <p>4 Q. I'm not looking at the study.</p> <p>5 Are you familiar with the word</p> <p>6 "indolent"?</p> <p>7 A. Indolent. Yes.</p> <p>8 Q. Indolent. Sorry.</p> <p>9 What does that mean?</p> <p>10 A. Yeah. Indolent generally means,</p> <p>11 you know, very slow growing or not -- you know,</p> <p>12 it's something on that spectrum. Not really --</p> <p>13 not actively showing significant growth or very</p> <p>14 slow growing. That's usually how indolent is</p> <p>15 used.</p> <p>16 Q. Can you see here in the study side</p> <p>17 where they talk about rapidly growing tumors</p> <p>18 among studies conducted in Asia -- sorry, in</p> <p>19 recent studies with diverse liver disease</p> <p>20 etiologies reported more indolent growth among</p> <p>21 patients with nonviral liver disease.</p> <p>22 What is "nonviral liver disease"?</p> <p>23 A. Nonviral means not related to</p> <p>24 Hepatitis B or Hepatitis C.</p> <p>25 Q. And so HCCs that are not related to</p>	<p style="text-align: right;">Page 412</p> <p>1 to -- again, there's multiple risk factors, but</p> <p>2 I think the primary one is his MASH-related</p> <p>3 cirrhosis. Yeah.</p> <p>4 So I mean, but -- but I think we</p> <p>5 were highlighting his -- he's more likely to</p> <p>6 have a slow-growing tumor. So -- so there's</p> <p>7 less reason to assume that he would have</p> <p>8 extremely rapid growth.</p> <p>9 He's more likely to be on the side</p> <p>10 of the distribution of a slow-growing tumor,</p> <p>11 which, again, is modeled in that table I showed</p> <p>12 you. So if we took, you know, the assumption</p> <p>13 of slow growth, which is 5.3 months, then we</p> <p>14 absolutely would have expected that he -- you</p> <p>15 know, he would have had, you know, lesions in</p> <p>16 the liver at that time.</p> <p>17 So I think that's, once again,</p> <p>18 consistent with what I'm -- what I'm modeling</p> <p>19 here.</p> <p>20 Q. And so if we go with the slow</p> <p>21 growth, which would be what you would expect</p> <p>22 with HCC from someone with NASH, when the</p> <p>23 radiology report from 4/18/16 was done, he</p> <p>24 should have nearly a 2-centimeter tumor at that</p> <p>25 time, right?</p>
<p style="text-align: right;">Page 411</p> <p>1 Hep A or -- sorry. Scratch that.</p> <p>2 HCCs that are not related to Hep B</p> <p>3 or Hep C typically grow slower, correct?</p> <p>4 A. Yes. I'd say so.</p> <p>5 Q. And the study authors say that's</p> <p>6 particularly important in the western world.</p> <p>7 That's here in the United States</p> <p>8 right, the "western world"?</p> <p>9 A. Yes.</p> <p>10 Q. Where -- where HCC is increasingly</p> <p>11 related to nonviral etiologies such as NASH and</p> <p>12 alcohol-related cirrhosis.</p> <p>13 And so is this saying that HCC that</p> <p>14 is related to NASH is typically slow-growing?</p> <p>15 A. Yes. That's --</p> <p>16 MS. ROSE: Object to the form.</p> <p>17 THE WITNESS: It's fair to say that</p> <p>18 HCC in NASH is typically more slow-growing</p> <p>19 than what you would observe in viral</p> <p>20 hepatitis-related HCC.</p> <p>21 BY MR. VAUGHN:</p> <p>22 Q. And it's your opinion that</p> <p>23 Mr. Roberts' HCC is related to NASH, correct?</p> <p>24 A. Yes. My opinion is that HCC in</p> <p>25 Mr. Roberts' case -- well, it's -- it's related</p>	<p style="text-align: right;">Page 413</p> <p>1 MS. ROSE: Object to the form.</p> <p>2 THE WITNESS: So look, these are</p> <p>3 not guaranteed -- guarantees. There's</p> <p>4 variation within every etiology of liver</p> <p>5 disease. It's not like every single</p> <p>6 patient with NASH-related cirrhosis will</p> <p>7 have a growth rate of 5.3 centimeters.</p> <p>8 There's inherent variability based on</p> <p>9 myriad factors.</p> <p>10 So, you know, all this is</p> <p>11 communicating is that it's more likely</p> <p>12 than not that he already had</p> <p>13 hepatocellular carcinoma present in the</p> <p>14 liver when he was first exposed to NDMA.</p> <p>15 There's going to be variation in</p> <p>16 what the actual size of the lesions might</p> <p>17 have been. There's -- and, of course,</p> <p>18 there's error introduced by the assumption</p> <p>19 of a sphere.</p> <p>20 So this is not a perfect</p> <p>21 prediction. But in the plausible ranges</p> <p>22 of where most patients fit -- and in</p> <p>23 particular patients with NASH or</p> <p>24 MASH-related cirrhosis, as you've</p> <p>25 highlighted, where the tumors grow more</p>